AOS

ADVANCED ORTHOPAEDIC SOLUTIONS

MAR 2 8 2013

8. SPECIAL 510(K) SUMMARY

SUMMARY PREPARED ON: March 7, 2013

SUBMITTED BY:
Advanced Orthopaedic Solutions, Inc.
386 Beech Avenue, Unit B6
Torrance, CA 90501
Phone: (310) 533-9966

CONTACT PERSON:
Allyson Parks
Advanced Orthopaedic Solutions, Inc.
386 Beech Avenue, Unit B6
Torrance, CA 90501
Phone: (310) 533-9966

DEVICE NAME: AOS 12mm and 13mm Tibial Nails
COMMON NAME: Rod, Fixation, Intramedullary and Accessories
CLASSIFICATION: Class II, 21 CFR 888.3020 Intramedullary fixation rod

DEVICE CODE: HSB

SUBSTANTIALLY EQUIVALENT DEVICE: AOS Tibial Nail System (K070444, June 14, 2007)

DEVICE DESCRIPTION:
The AOS Tibial Nails are intramedullary fixation devices for the temporary fixation of various types of fractures of the tibia and are intended as load sharing devices which may be removed once the fracture has healed. The AOS Tibial Nail System consists of titanium intramedullary nails, proximal and distal locking screws, and end caps.

This Special 510(k) proposes the addition of 12mm and 13mm diameter nails to the system.

INDICATIONS FOR USE:
The AOS Tibial Nail System is intended to provide temporary stabilization of various types of fractures, malunions, and nonunions of the tibia. The AOS Tibial Nail System is indicated for long bone fracture fixation of tibial fractures, which may include the following: transverse, oblique, spiral, segmental and comminuted fractures; fractures with bone loss and bone transport; open and closed fractures, pathologic fractures; corrective osteotomies; pseudarthrosis of the tibial shaft; nonunions, malunions, metaphyseal and epiphyseal fractures.

SUBSTANTIAL EQUIVALENCE: Information presented supports substantial equivalence of the 12mm and 13mm Tibial Nails to the predicate device. The proposed nails have the same indications for use, are similar in geometry and design, have the same fundamental scientific technology, and are made of the same material (Ti-6Al-4V ELI, per ASTM F136) as the predicate nails. As detailed in the submission, the proposed nails do not present a worst-case scenario with respect to strength characteristics, and because of their similarity to the current nails, physical testing was deemed unnecessary, and substantial equivalence was determined in strength and geometry between the proposed nails and the predicate nails.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Advanced Orthopaedic Solutions, Incorporated
% Ms. Allyson Parks
Regulatory Associate
386 Beech Avenue, Unit B6
Torrance, California 90501

Letter dated: March 28, 2013

Re: K130625
Trade/Device Name: AOS 12mm and 13mm Tibial Nails
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: March 7, 2013
Received: March 18, 2013

Dear Ms. Parks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

AOS

ADVANCED ORTHOPAEDIC SOLUTIONS

7. INDICATIONS FOR USE STATEMENT

Special 510(k) Premarket Notification
Indication for Use Statement
AOS 12mm and 13mm Tibial Nails

510(k) Number (if known): K130625

Device Name: AOS 12mm and 13mm Tibial Nails

Indications for Use:

The AOS Tibial Nail System is intended to provide temporary stabilization of various types of fractures, malunions, and nonunions of the tibia. The AOS Tibial Nail System is indicated for long bone fracture fixation of tibial fractures, which may include the following: transverse, oblique, spiral, segmental and comminuted fractures; fractures with bone loss and bone transport; open and closed fractures, pathologic fractures; corrective osteotomies; pseudarthrosis of the tibial shaft; nonunions, malunions, metaphyseal and epiphyseal fractures.

Prescription Use: X AND/OR Over-The-Counter Use: ____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopaedic Devices